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09/529,742    07/24/00    RUDIN

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| EXAMINER |
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|          |              |
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| ROSE, S  |              |
| ART UNIT | PAPER NUMBER |

1614  
DATE MAILED:

8  
06/21/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/529732

Applicant(s)

RUDIN et al

Examiner

SIEB ROSE

Group Art Unit

1614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1810 is/are pending in the application.  
Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1810 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

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This application filed by Rubin et al on July 24, 2000 claims ~~an~~ October 17, 1997 priority date and presents ten composition claims.

Claims 1 to 7 read on these known ultra finely divided hydroxyapatite particles per se of the claim recited average particle size length, width, and height, admittedly known for non-stomatic applications, the intended use recited in the claim preamble. Claim 8 reads on zero amounts of the recited substances. Claim 9, line 2 should add--effective amounts-- after "by", (as should claim-10).

It is admitted prior art, set forth in the specification, on page 1, as "prior art" that larger particle size hydroxyapatite particles, are known stomatic compositions, from EP 0344832 and from EP 0342726.

Applicants PTO-1449 IDS cited three (3) items of art:

Rubin et al WO 98/18719 published May 7, 1998 seems to correspond to this application.

Does it? Does it correspond to any pending U.S. patent application?

17 Rubin et al EP 664133 published July 25, 1995 (by applicants herein) describes these known ultra finely divided hydroxy apatite particles (0.015-0.06 mm).

Sangi LTD, EP 786245, publishes July 30, 1997 describes these knows ultra finely divided hydroxyapatite particle.

19 Atsumi et al U.S. 5833959, filed January 23, 1997, patented November 10, 1998, seems to be the U.S. counterpart of Sangi EP 786245, published July 30, 1997.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 to 8, 10 rejected under 35 U.S.C. 102(a) (b) (e) as being anticipated by Sangi EP 786245, Atsumi et al U.S. 5833959 and Rubin et al EP 664133 (details as noted above).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 to 8, 10 rejected under 35 U.S.C. 103(a) as being unpatentable over Rubin et al EP 664133 taken with Atsumi et al U.S. 5833959 (or Sangi EP 786245) and additionally in view

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of dentifrices with the claim 8 and claim 10 agents with layer particle size hydroxyapatite,  
2 cumulative to the admitted prior art, set forth on page 1 (as noted above), in each of Scheller (I-  
3 II), Bristow et al (I-II-III), Coulson (I-II) and Aoki. These are obvious combinations of  
4 ingredients, with no showing of criticality of the particle size claimed.

The statement on page 1, first sentence, "--and curing of caries, periadenitis, and  
paradentosis--" should be revised by deleting --and curing--, and here there should be added the  
three paragraphs on the bottom of page 8 and page 9.

The spelling of "chewing gum" should be corrected on page 9, line 6.

An abstract of the disclosure is needed.

This application does not contain an abstract of the disclosure as required by 37

CFR 1.72(b). An abstract on a separate sheet is required.

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the  
compound or composition should be given as well as its use, *e.g.*, "The compounds are of the  
class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species  
could be illustrative of members of the class. For processes, the type reaction, reagents and  
process conditions should be stated, generally illustrated by a single example unless variations are  
necessary.

Complete revision of the content of the abstract is required on a separate sheet.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a  
separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed  
250 words in length since the space provided for the abstract on the computer tape used by the  
printer is limited. The form and legal phraseology often used in patent claims, such as "means"

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and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

#### PRIOR ART ADMISSIONS

An admission relating to the prior art is a fact which is a part of the scope and content of the prior art which every examiner is required to consider. Ex parte McGaughey, 6 USPQ 2d 1334, at 1338/1339, In re Thompson 192 USPQ 275, In re Nomiwa 184 USPQ 607, In re Davis, 134 USPQ 256, 285.

It was admitted as prior art on page 1 that dentifrices with the excipients of claims 8 and 10 have been described with larger particle sized hydroxyapatite, and there is no showing of criticality of the particle size claimed.

#### OBVIOUS COMBINATION CASE LAW

As stated in In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA-1980):

" . . . It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. As this court explained in Crockett, 126 USPQ 186, 188 (CCPA-1960), the idea of combining them flows logically from their having been individually taught in the prior art.

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Likewise, see In re Pinten, 173 USPQ 801, 803 (CCPA 1972); and In re Susi, 169 USPQ 423, 426 (CCPA-1971).

As noted above, claims 1 to 7 differ from Rubin et al EP 664133 (7/25/95) only by a statement of intended use in the preamble of the composition "for stomatic applications" a term that encompasses dentistry other than oral care as set forth on page 9 of the specification, as in this prior art reference.

Claiming an unpatentable old compound, in combination with a carrier, does not render the combination patentable, if it would be obvious to utilize a carrier with a compound. In re Rosicky, 125 USPQ 341; In re Lerner, 169 USPQ 51; Ex parte Douros et al, 163 USPQ 667; and In re Craige, 89 USPQ 609; unless the prior art has a negative teaching that the compound was "pharmacologically inert", In re Wiggins, 158 USPQ 199, Ex parte Frohberger, 168 USPQ 376, or, if use of the specific carrier would not be obvious.

The intended use of an old composition does not render composition claims patentable, in re Zierden, 162 USPQ 102, 104, and the mere preamble statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable, In re Sinex, 135 USPQ 302-305.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday<sup>Tues day</sup> / Thursday from 7:30 am to 6 pm

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.



Shep Rose  
Senior Primary Examiner  
Art Unit 1614

SKR: mv  
June 8, 2001

**SHEP K. ROSE  
PRIMARY EXAMINER  
GROUP 1200**